

What is claimed is:

1. A balloon catheter comprising an inflatable balloon consisting essentially of at least one metal.

2. The catheter according to Claim 1, wherein the at least one metal is selected from the group consisting of titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof.

3. The catheter according to Claim 1, wherein the inflatable balloon has a wall thickness between about 3 μ m and 10 μ m.

4. The catheter according to claim 1, wherein the inflatable balloon deflates under the influence of at least one of a shape memory, superelastic or elastic property of the at least one metal.

5. The catheter according to Claim 1, further comprising a catheter body fabricated from a material selected from the group consisting of polymers and metals.

6. The catheter according to Claim 1 made by the method comprising the steps of:
vacuum depositing a film of the at least one metal onto the generally cylindrical mandrel having a geometry desired for the inflatable balloon to form the inflatable balloon; and

removing the generally cylindrical mandrel from the formed inflatable balloon.

7. The catheter of claim 1, further comprising a catheter body member having an inflation lumen and at least one inflation port, wherein the at least one inflation port is in fluid flow communication with an inflation lumen of the inflatable balloon.

8. The catheter of claim 1, wherein the inflatable balloon is formed of plural layers of the at least one metal.

9. The catheter of claim 1, wherein the inflatable balloon further comprises a plurality of perfusion ports passing through the inflatable balloon and facilitating fluid flow communication between outside and inside the inflatable balloon.

10. The catheter of claim 1, wherein the inflatable balloon further comprises a plurality of generally linear projections emanating from an exterior surface of the inflatable balloon and extending along a longitudinal axis thereof.

11. The catheter of claim 10, wherein adjacent pairs of generally linear projections define fold lines for the inflatable balloon.

12. The catheter of claim 10, wherein the longitudinal projections form a geometric pattern that is physically complementary to an implantable device that rests on the inflatable
5 balloon and is delivered by the catheter.

13. The catheter of claim 1, wherein the at least one metal is comprised of a radiopaque metal.

14. The catheter of claim 1, further comprising a coating of biocompatible elastomer encapsulating the inflatable balloon.

10 15. The catheter of claim 1, wherein the inflatable balloon has conductive properties for transmitting energy delivered from an external source.

16. A catheter for localized delivery of a bioactive agent comprising a drug-eluting balloon having a first balloon and a second balloon, having a plurality of pores passing therethrough, concentrically positioned over the first balloon in a spaced apart relationship
15 defining an annular lumen therebetween, at least one pharmacologically active agent disposed within the annular lumen and elutable through the second balloon, each of the first and second balloon consisting essentially of at least one metal.

17. The catheter of claim 16, further comprising an inflation lumen and an inflation port, the inflation port being in fluid flow communication between the inflation lumen and the
20 first balloon.

18. The catheter of claim 17, further comprising an introductory lumen in fluid flow communication with the annular lumen such that a pharmacologically active agent may be introduced into the annular lumen through the introductory lumen.

19. The catheter of claim 16, wherein the plurality of pores are dimensioned to permit
25 elution of the at least one pharmacologically active agent only upon application of a positive pressure to the first balloon.

20. The catheter according to Claim 16, wherein the at least one metal is radiopaque.

21. The catheter according to Claim 16, wherein the at least one metal is selected from the group consisting of titanium, vanadium, aluminum, nickel, tantalum, zirconium,
30 chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof.

22. The catheter according to Claim 16, wherein the first balloon and the second balloon have wall thicknesses between about 3 μ m and 10 μ m.

23. The catheter according to claim 16, wherein both the first and second balloons deflate under the influence of at least one of a shape memory, superelastic or elastic property of the at least one metal.

24. The catheter according to Claim 16, further comprising a catheter body fabricated of a material selected from the group consisting of polymers and metals.

25. The catheter according to Claim 16 made by the method comprising the steps of:
vacuum depositing a first film of metal onto a generally cylindrical mandrel having a geometry desired in the first balloon to form the first balloon;

depositing a sacrificial layer onto the surface of the first balloon to assume the desired geometry for the second balloon;

vacuum depositing a second film of metal onto the sacrificial layer to form the second balloon; and

removing the formed first and second balloon by eliminating the sacrificial layer and releasing the formed first and second balloon from the generally cylindrical mandrel.